
Ethical Considerations in the Design and Execution of the National and Hispanic Health and Nutrition Examination Survey (HANES)

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The purpose of this article is to describe some ethical considerations that have arisen during the design and implementation of the health examination surveys conducted by the National Center for Health Statistics of the Centers for Disease Control and Prevention. Three major areas of concern are discussed: sharing information from the study, banking and using banked tissue samples, and obligations for future testing of subjects. Specific concerns of sharing information include: when to inform, whom to inform, maintaining confidentiality, and how to inform individuals. Specific concerns of determining when sera will be banked and using banked samples include: depletion of samples for quality control, obtaining informed consent for unanticipated uses, access by others, and requests for batches of samples. Finally, specific concerns regarding future testing of subjects include: retesting for verification, retesting for interpretation, testing for different risk factors, and follow-up. Although existing surveys can provide experience or even suggest guidelines, the uniqueness of any new survey will generate unique ethical problems, requiring the careful formulation of unique solutions. — *Environ Health Perspect* 103(Suppl 3):75–80 (1995)

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Introduction

The purpose of this article is to provide a perspective on the theoretical discussions of ethical concerns of studies by discussing a case study, the examination surveys conducted at the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention. Of course, the discussion of a case study will not provide answers for other studies, but it will illustrate the need for discussions focused on ethical issues during the development of research protocols. Also, the description of situations that have arisen in the NCHS experience may broaden the perspective of investigators and make them sensitive to potential new issues.

This article will not be an exhaustive discussion of issues that have been confronted by NCHS examination surveys. Rather, three major concerns will be

addressed: sharing information from the study, specimen banking and using banked tissue samples, and obligations for future testing of subjects.

Survey Description

The National Center for Health Statistics is one of the major federal statistical organizations. It has legislative authority to collect statistics on the extent and nature of illness and disability in the United States (including life expectancy, the incidence and prevalence of acute and chronic illness and disability, and infant and maternal mortality and morbidity); determinants of health; health resources; use of health care resources (including use of ambulatory services, hospital care, nursing homes, and other long-term care facilities); health care costs and financing; and family formation, growth, and dissolution (*1*). In summary, NCHS has the mandate to describe the health and health experience of the American public. This is in contrast to other agencies that target data collection on individuals with certain health conditions or diseases or study the clinical experience of patients.

NCHS carries out its mission through the conduct of many annual, periodic, and longitudinal data systems and surveys. Information is collected from vital records, administrative records, interviews, and examinations. The Center also maintains an inventory of health facilities. The focus

of the discussion in this article is on the examination surveys.

The National Health and Nutrition Examination Surveys (NHANES) are designed to periodically assess the health and nutritional status of adults and children in the United States through interviews and direct physical examinations. The detailed interview includes demographic, socioeconomic, dietary, and health-related questions. The examination component consists of medical and dental examinations, physiologic measurements, and laboratory tests administered by trained medical personnel in mobile examination centers. Individuals are identified for participation in the surveys based on census information, such that the resulting study population is representative of the age, race, and sex distribution of the United States. A complex, stratified sampling design is used.

In addition to the NHANES, a similar survey was performed in the early 1980s that targeted Hispanic populations in the United States. This survey is referred to as the Hispanic Health and Nutrition Examination Survey (HHANES). Collectively, the examination surveys will be referred to as HANES in the following text.

To understand the ethical issues that will be discussed below, it is helpful to understand the procedures of the survey. As noted, households and individuals within households are selected by the Bureau of Census to reflect the national

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and regional age, race, and sex distribution of the noninstitutionalized civilian American public. In various surveys, special populations, such as low income or minority populations, have been emphasized using stratified sampling. Household interviews are conducted and selected individuals from the household are invited to undergo a detailed physical examination in a mobile examination center (MEC). The examination is an extensive process conducted by a survey team consisting of a physician, dentist, medical and health technicians, and dietary and health interviewers. All testing equipment is contained in the MEC. In recent surveys, elderly and disabled subjects who were not able to come to the MEC could receive a partial examination in the home. The interviewers and examination trailers travel together to locations determined through the multi-stage, stratified sampling procedures.

As part of the physiologic assessments, HANES collects samples of blood. The blood is collected in a variety of vacutainer tubes so that samples are available as whole blood and serum; where appropriate, a variety of anticoagulant chemicals are used. Each of these samples is used for specific determinations and sufficient samples are collected so that repeat determinations can be performed. However, after processing by the laboratories, residual amounts of these samples are sometimes available. These samples have been collected from the laboratories participating in the HHANES and NHANES III and placed in sera storage banks. The amounts of tissue available vary considerably between subjects.

The HANES program seeks advice on ethical issues from an Institutional Review Board, consisting of researchers from other programs in NCHS and from nongovernment institutions, in addition to medical professionals and lay individuals. HANES staff also occasionally seeks input from other institutional review boards, such as the board advising the National Institutes of Health, to obtain a broader consensus on some issues. All of the boards follow advice from such federal and internationally recognized deliberations as for instance, the Privacy Act of 1974, confidentiality considerations of the Public Health Service Act (section 308D), and the Belmont Commission's report (2).

Sharing Information

Several questions revolve around sharing information from a study, including when to inform, whom to inform, how to

inform, and maintaining confidentiality of the information.

When to Inform

On the surface, it might appear that the answer to the issue "when to inform" is "always." But that is not strictly true. Consider a situation when either the information is uninformative or the subject cannot act on the information. In such a situation, it is not clear whether it is appropriate to inform the subject and, therefore, possibly engender concern. Certainly, information should be shared when the health status of the subject is known to be at risk. In the HANES program, there are three levels of need for information sharing.

The most urgent level of need is when an emergency arises in the MEC. In those instances, transportation is immediately arranged for the subject to the appropriate health care facility or social services unit and information regarding the health status and testing results are given to the subject to transmit to the appropriate personnel at the receiving facility.

For a majority of the laboratory and examination assessments performed as part of the HANES, standard interpretations of the findings exist. For these assessments, there is general agreement regarding threshold or reporting levels. Consequently, these findings are shared with the subject. When the findings are abnormal, a Rapid Reporting System is used to contact the subject as early as possible after the findings are noted. The subject is given information on possible next steps she or he might pursue to obtain further evaluation of the findings and their implications. For those subjects whose findings were in the normative range, the subjects are also informed of the results, but not as rapidly as those with abnormal findings.

However, for some assessments performed as part of the HANES, there are no clear interpretations of the findings or agreed-upon critical levels. In such cases, it is difficult to interpret the findings to the subject. Such an assessment might be included in the HANES because of research needs or the need to determine the distribution in the general population. For instance, when lead was originally being assessed in tap water as part of NHANES I (1971–1975), there were no clear guidelines as to reportable levels. Similarly, the implications of the presence of prostate-specific antigen, considered but not included in NHANES III, are unclear. The approach HANES has taken is to report to

subjects the findings for clinically accepted assessments, but not for research-based findings. Burdening a survey with research-based protocols can weigh a study down with trying to address concerns of the subjects regarding the interpretation of the findings. It should be considered whether a survey is the appropriate mechanism for this kind of research.

Whom to Inform

Another ethical issue that will be a major concern for surveys of exposure and risk assessment is whom to inform. Information from other data systems on many sources of exposure are available to the larger community, for instance, air pollution or water pollution. In general, HANES has not evaluated these forms of public exposure. However, as noted above, in NHANES I, tap water in the subject's home was assessed for several possible contaminants. In fact, no violations of contaminant levels were found. However, the survey was very concerned with whom to inform should high levels be detected. In many instances, the subject does not own the home or is renting an apartment. Should the homeowner or building manager be informed? A further complication is that the survey is conducted in many states, and laws differ between states. Therefore, it was conceivable that a level of contaminant might be observed that was not in violation of levels in the state in which the subject resided, but would have been in violation of levels in other States. Would it have been the responsibility of the survey to inform the subject that the level detected would have been in violation elsewhere? If a violation had been detected, another complication arises in the determination of who is responsible to fix the situation. Is it the responsibility of the homeowner or the water treatment facility? These were issues which the survey did not have the expertise to address. Fortunately, the occasion never arose. However, this means that researchers have never clearly determined the extent to which these surveys of personal health status and personal risk behaviors are responsible for the evaluation and interpretation of non-personal risk factors. In future exposure and risk surveys, these ethical issues must be addressed.

Additional complications arise when the exposures are based on self-reporting by the subject, that is, when the exposures are perceived exposures. For instance, in the HHANES the subjects were asked if they had been sprayed by chemicals while

working in the agricultural fields. If such an exposure were reported, should it be reported and to whom? Several possibilities exist. For instance, the local occupational safety and health agency might be informed or the employer might be informed. There was concern that subjects might lose their jobs if the officials or employer were informed. To obtain unbiased answers, it was explained to the subjects that only they would receive the individualized information from the study. Another concern for the survey was the family members who might also have been exposed due to chemicals remaining on the clothing of the worker. However, this could not be verified. Another example of self-reported exposure is a question included in the NHANES III regarding tobacco smoke exposure at work. In some states there are laws requiring the employer to provide a smoke-free environment. When smoke exposure was reported by a subject, was it the responsibility of the survey to inform the state or the employer? Should the survey inform the subject that these laws exist?

A new set of complications is arising as surveys contemplate the use of DNA to assess biologic markers. DNA is a very personal thing, but not a private thing. The DNA of the individual is shared to varying degrees with family members. The issue that must be addressed arises in the situation when an adverse genetic result is found. This situation has not yet arisen for HANES because, at this time, DNA has been stored, but not analyzed. If, however, an adverse genetic result were found, what are the responsibilities of the study to inform family members of their possible risk? In genetic counseling, the usual practice is to inform the patient and allow the patient to determine whether and by whom other family members will be informed.

State and local governments often have concerns regarding the findings of specific assessments. For instance, many states have laws regarding the reporting of blood lead levels in children and in adults. NHANES II, Hispanic HANES, and NHANES III have all assessed lead in blood tissue samples. Because HANES is conducted by a federal agency that is not subject to state jurisdiction, it is the policy of HANES to provide the test results to the individual and, if these blood lead levels were high, to provide information regarding the agencies that are concerned with the determination and followup of individuals with high blood lead levels. It is then

the responsibility of the individual to contact the agencies.

Indeed, the reporting of adverse (and even normal) findings has been an evolving procedure over the years, even for standard clinical assessments. In earlier surveys, HANES provided the clinical findings to the physician of note. However, this engendered several problems. In most instances, the physician did not want the information because it transferred some implied liability to the physician. Often the general practitioner did not know enough to adequately interpret the findings. Then, when the doctor sent the findings to specialists for their interpretation, the subjects would receive bills. Sometimes the doctors would feel it necessary to repeat the test with their own laboratory, again generating bills for the subject, often unnecessarily. Sometimes the doctor would fear liability for not having performed the assessment, even if the subject was clinically asymptomatic. As a result, the procedure of providing results to the physician was abandoned. Today, results are provided to the subject, with advice on possible next steps.

The family is often an interested party, not only in the case of the DNA studies noted above, but also when previously unrecognized disease states or risk factors are found. Obviously, the family would share the burden of an ill family member. However, it has been the policy of HANES to inform only the subject and allow the subject to determine whether family members should be informed. An exception to this, of course, is when the subject is a child.

Another situation that has arisen is when the subject applies for insurance, subsequent to participating in the study, and does not want to undergo another examination. They may request that the findings be sent to the insurance company. Again, it is the HANES policy to send information to the subject and then the subject determines what should be done with that information.

In summary, it is the policy of HANES to inform only the subject, unless there is an emergency situation and other authorities need to be informed. This, however, will not be the situation for all surveys. Some surveys may be subject to local and state laws. The determination of whom to inform should be continually reevaluated by study investigators.

Maintaining Confidentiality

With regard to the issue of maintaining confidentiality, for the HANES surveys,

the subject is the gate through which the information must flow. With regard to the production of computer data tapes, there are standard regulations regarding the limitation of personal identifiers, so the subject is unlikely to be identified. This becomes a complex issue, however, when the data are linked to other data systems. It is conceivable that enough detailed information could be linked so that the probability of identifying individuals is actually improved. In those instances, the data need to be made available in different formats. For instance, data can be aggregated over years or over geographic areas, with the appropriate variables suppressed so that identification is less likely. However, for a multifaceted study that assesses the health status of the subject and characterizes the environment, as has been proposed by the U.S. Environmental Protection Agency, maintaining confidentiality will not be a simple issue.

How to Inform

It is of the utmost concern that the subject never be labeled, i.e., never be "diagnosed," by a general health survey such as the HANES studies. Rather, the subject is informed that a finding is abnormal and that medical advice and follow-up should be sought. There are several reasons why a diagnosis is not used. First, there may be extenuating circumstances unknown to the MEC staff that would have led to this finding. Second, additional tests may be required to determine the diagnostic status of the individual. Third, "diagnoses" may be misunderstood by third parties, such as insurance companies. An interesting, but disturbing, future situation might arise if insurance companies start using genotype information as if the genotypes were "diagnoses" rather than risk factors. In most instances, the genotype does not confer an inevitable health status on the subject, but rather imparts information regarding the risk for a subject to have an altered health state. In that sense, therefore, the genotype is a risk factor, not a diagnosis.

The ability to provide counseling for the subjects is limited in the HANES program. The individual is sent a letter in which great care is taken to explain the potential ramifications of findings in language that might be understandable to the lay reader. Telephone numbers are available for the subject to call staff, including medical officers, and ask questions. In addition, when appropriate, the letter provides information on agencies and telephone numbers where the subject can

follow up on the finding. However, by the time this information is available and sent to the subject, the MEC has moved to another city, often another region of the country. Therefore, there is no opportunity to speak face to face with the subject. Because extensive counseling is not possible, clinically meaningful and interpretable findings, rather than research-driven findings, are shared with the subject. The subject has a better chance of obtaining additional counseling and information regarding the clinically meaningful findings than research-based findings.

The issue of what to share and how to share information with the subject should be a major issue for any survey and will be driven, in part, by the study's purpose. If a survey obtains information for which the consequences are largely unknown, it would be well to consider how the subject would benefit from the survey. It is important for researchers and public health officials to provide subjects with some immediately useful information in exchange for their participation.

Banking and Using Banked Tissue Samples

A central focus of this conference was tissue banking. However, the banking of tissues is not always the primary objective of a study. Therefore, determining when sera are available for specimen banking and using those banked tissue samples can be an ethical concern for such a study. Four aspects of this concern are discussed here: the depletion of samples for quality control studies, obtaining general informed consent, access by others, and requests for batches of samples.

Quality Control

The issue of depleting stores of banked samples for quality control purposes is a simple one for HANES—there are no “surplus” sera until the whole protocol is completed and quality information obtained. It is a tacit agreement of the HANES program with the subjects that the laboratory analyses will be performed with appropriate quality control. HANES generally obtains enough tissue to conduct the quality control assessments and repeat assessments that are required (also see the Survey Description section). However, if additional, multiple tests were required to obtain quality information and, hence, deplete the sera, the multiple tests would be performed and the sera depleted. Only after quality data have been obtained on all the assessments would sera be declared

surplus and then stored. Requests for use of the sera are reviewed at that time. In summary, quality control of all tests is the primary objective of the HANES. Banking of remaining tissue samples has not been a primary focus of the surveys.

Informed Consent

Obtaining informed consent for unanticipated uses is a difficult issue. Although there are general phrases included in most informed consent forms, the extent to which these capture and the subjects understand the possibilities and ramifications is often unknown. Often we, as researchers, just wave our hands and say, “We have the appropriate phrases in the consent form,” without careful considerations of what the subject does, or should, understand. An example of misunderstanding that can arise is the following. In one instance, the HANES sera were tested for indications of exposure to a sexually transmitted disease. Several individuals were found to be positive, even after repeated testing of the samples. One individual who was found to be positive was a lady who expressed shock and dismay and claimed that she certainly would never have put herself in a position to make it possible for such a thing to happen. She did not understand the possibilities of future testing of her sera. In NHANES III, testing of human immunodeficiency virus (HIV) and drug substances are done anonymously. The decision to perform these tests anonymously was based on a number of considerations, including the inability of the survey to provide counseling and the possibility that subjects would refuse to participate in this testing, given the current cultural context.

Another issue of informed consent is to what extent the study should save the sera for future, perhaps more sensitive and accurate, laboratory testing and to what extent the subject should be informed of this possibility. In some university-based programs, subjects have said that they gave blood because they knew the investigators were on the forefront of research and, if a new procedure became available, the researchers would be likely to perform the test before their family doctor would. The implication was that, if anything abnormal were found, the investigators would tell the research subject right away. These subjects did not understand that even if new procedures were used, because these new procedures are largely untested, the implication of the findings is usually unclear. Such additional testing cannot be guaranteed by

a general health survey. In fact, new laboratory procedures are sometimes used on the sera in the tissue bank, but because tissues are not available on all subjects, the testing of any one subject cannot be guaranteed.

Access to Banked Samples

The HANES studies are conducted with the understanding that HANES “owns” the samples. Over the years, HANES has had a number of unusual requests for uses of the banked samples. There are many possible requests that HANES has not received but that should be considered by investigators. Samples might be requested, following the death of the subject because the sample was needed to resolve a medical issue regarding conditions existing before the death. Private industries or economically self-interested groups, in addition to university-based researchers, might request batches of samples to run special research protocols. In fact, all requests are evaluated regardless of the source of the request. The requests are evaluated for scientific merit, including the appropriateness of the survey to answer the question of the investigator, and availability of surplus sera. If the research protocol is found to be appropriate, samples are provided to the researchers without personal identifiers.

Family members might request aliquots of surplus sera. This type of request could happen with any tissue samples, but interesting new problems arise when DNA (or white blood cells) are being stored. Unlike most other analyses, the subject's DNA genotype may have direct relevance for the health of the requestor. For instance, if a genetic defect is known to be present in the family and the subject refused to be tested as part of the family studies performed by the genetic counselor, the family might request that testing be performed on the stored DNA. This situation has not arisen for the HANES program, but ethical issues regarding the use of DNA samples currently are being explored.

Requests for Batches

Requests for batches of samples to conduct research are appropriate. HANES receives more requests than they have sera to satisfy them. Therefore, it is important that a well-organized procedure be established to determine whether requests for batches of banked sera are appropriate. Reviews of requests include external experts in addition to staff of the survey. The HANES program uses the following criteria to determine the acceptability of a request: the public health significance, scientific

merit, and practical utility of the assay; the sampling scheme (random samples receive high priority); characteristics of the specimen such as volume and impact of the freeze-thaw cycles and protocols used during storage; and number of assays performed (multiple analytes determined from one sample are given higher priority).

One aspect that might be considered in a discussion of ethical issues is whether targeting special population groups in excess sera batch requests is appropriate when the original study did not target that group. As noted above, the HANES gives high priority to requests for random samples of the survey because batch requests for targeted special subgroup analyses decrease the potential representativeness of the surplus sera. That is, the use of parts of the national sample for studies of special subpopulations means that the reserved sera for those subjects are depleted more rapidly. Consequently, other requests for random samples of the population might not be possible to provide because of sera missing from segments of the population. The other disadvantage of targeting special subpopulations for some research protocols is that important research data are not derived for the other segments of the population. This, of course, has been one of the arguments recently put forward regarding health research and women.

There are, however, reasons for focusing on subgroups in the population. For instance, there is much concern in environmental research for toxicant doses received by children and by women during their reproductive years. Doses received by the elderly might be of equal concern, however, given their general lack of reserves and, hence, greater sensitivity to environmental insults. Exposures to men and middle-aged individuals should not be ignored. Socially disadvantaged populations might experience unusual exposures. Obviously, one way to accommodate the focused study on special populations is to design the survey to oversample these populations. However, given limited resources and lack of general clairvoyance with regard to future issues, appropriately banked sera are usually not available. The conflicting uses of banked sera to address research questions for which the collection of sera was not designed is an ethical issue that needs to be addressed as we embark on more large surveys. The effort involved in the design, collection, and maintenance of these surveys and banked tissues means that we will get few opportunities to collect such data. These well-designed tissue banks

become very valuable resources, but they are valuable only to the extent to which they are utilized. Blanket refusal to provide sera except for very limited research designs is not appropriate either.

Obligations for Future Testing

Finally, the obligation for future testing takes several forms. A variety of situations might be considered: retesting for verification, retesting for interpretation of findings, testing of different risk factors, and follow-up.

Retesting for Verification

The HANES program tries to collect sufficient samples on the initial contact to have tissue samples available for retesting for verification, should that be necessary. Hence, for HANES, the survey is conducted with the eye towards obtaining tissue samples only once from the subject. Retesting selected subjects for verification of test results is usually not possible because by the time test results are available the MEC has usually relocated.

Retesting for Interpretation of Findings

Retesting for interpretation of findings is a different issue. Retesting for interpretation is not necessarily the use of the same test at a later date on the individual, although it might be, as for instance, a second evaluation for high blood pressure. Retesting for interpretation might also involve the retesting of the individual using different procedures to assist in the interpretation of findings from the initial tests. An example is a recent request that HANES include evaluation for prostate-specific antigen. Although this was certainly possible with the protocol in place, the interpretation of the findings would require follow-up testing using, for instance, ultrasonography. That was not possible with the HANES design and, hence, the antigen testing was not included. Another example is the use of findings from the urine microalbuminuria assessments to retest subjects for glomerular filtration rates. With the National Institutes of Health, a protocol was attempted to provide glomerular filtration rate tests to selected subjects. However, given the scattered locations of subjects (NHANES III is going to approximately 30 states), it was impossible to provide these complicated tests at sites near the subject's residence and maintain quality control over the tests as well as the information provided to the subject by these associated centers.

Consequently, the HANES program has avoided the inclusion of assessments that require subsequent testing of subjects. In other studies, the possibility of retesting might be quite appropriate. But for studies in which retesting and supportive follow-up are not a viable option, the selection of tests to be included in the study should be evaluated in light of the implications of findings for the subjects and the burden, either psychological or financial, that might be placed on the subject.

Testing for Different Risk Factors

Another situation that requires retesting is the identification after the initial study has been completed of different risk factors. Often information on the different risk factors would be nice to have for interpretation of the study findings. The NHANES I has a longitudinal component and subsequent HANES have been planned with the possibility of longitudinal studies. One example of retesting for different risk factors is the collection of smoking information during the first wave of the NHANES I Epidemiologic Follow-up Study. In that study, which was performed an average of 10 years after the NHANES I, investigators attempted to collect information on the smoking status of the subjects at the time of the initial NHANES I examination. Smoking status had not been collected on all individuals in the initial examination. The HANES longitudinal studies, at this time, are limited to questionnaire follow-up. The ability to perform limited examinations is being evaluated. The ability to retest at later dates for either newly identified risk factors or subsequent health status is an important capability.

Follow-up

As noted above, the HANES program has incorporated a follow-up component largely limited to questionnaire information. Follow-up is generally conducted on the whole study population at the same time. A survey may become burdened if more flexible follow-up procedures are implemented. It should be remembered that the American population is highly mobile, and, after a couple years, many of the subjects may have moved, making follow-up of the entire cohort with other than mailed questionnaires virtually impossible. This means that the subsequent collection of tissue samples is not possible. Therefore, large tissue banks should be designed to include single samples from subjects. This will, of course, limit the types of research that can be conducted.

Possible nested designs might overcome these limitations to some extent.

It is important that subjects understand whether or not follow-up will be performed as part of the study and that they also understand the nature of the follow-up.

Summary

When approaching ethical issues, it should be kept in mind that the underlying tenet that motivates individuals to allow us, as

strangers, to obtain biological samples from them is trust. It is really remarkable that you can go knock on a door and someone will actually allow you to "use" him for, say, half a day as a subject in a survey, be it a government survey or other research-based survey. That is a trust we must honor. Hence, the commitment that we must have to drive our decisions regarding the use of those specimens and information obtained therefrom should be justice. In this case, the larger sense of the word

"justice" is meant, that is, open information exchange, fairness, and confidentiality. Having said that, it should be equally clear that each study must be resolved within itself. Certainly, existing surveys can provide experience or even suggest guidelines, but the uniqueness of any new survey will generate unique ethical problems, requiring the careful formulation of unique solutions.

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